Biogen v. Mylan (November 30), demonstrates the written description requirement in action and illustrates a classic tension between supporting written description while simultaneously trying to defeat obviousness.

Background: Facts & The Issue

Mylan sought to market a generic version of Biogen's multiple sclerosis drug Tecfidera®. Per the standard Hatch-Waxman process, Biogen sued Mylan for infringement of an Orange Book-listed patent. The district court determined that Biogen's patent was invalid for lack of adequate written description.

The claims recite a method of treating multiple sclerosis involving administering dimethyl fumarate[1] in the "therapeutically effective" dose of "about 480 mg" per day. That method is not expressly stated or exemplified anywhere in the specification, but there are several data points in the specification to which Biogen pointed to support satisfaction of the written description requirement:

- Multiple sclerosis is discussed in two paragraphs in the first column of the patent.
- The specification describes a method of treating neurological diseases in which dimethyl fumarate is administered.
- The specification describes an "effective dose" of dimethyl fumarate of "from about 480 mg to about 720 mg per day."
    - Biogen's expert testified that "a skilled artisan would be drawn to the [480 mg/day] dose because it was 'anchored' to the effective [720 mg/day] dose" via the described range of "from about 480 mg to about 720 mg per day."

Mylan questioned whether those data points were sufficient, and made several additional points:

- Although multiple sclerosis is discussed early in the specification, the description immediately broadens the focus to the underlying enzyme gene induction pathway[2] and a large number of other neurodegenerative and demyelinating diseases (*e.g.,* "amyotrophic lateral sclerosis (ALS), Parkinson's disease, Alzheimer's disease, and Huntington's disease; demyelinating neurological diseases, such as various forms of MS and at least twenty-eight other disorders related to demyelination; polyneuritis; and mitochondrial disorders with demyelination.").
- The reference to administering "from about 480 mg to about 720 mg per day" is the *only* reference in the specification to administering 480 mg per day, and the claimed dosage of about 480 mg/day is right at the bottom of that range.
    - In contrast, the only daily dose that is independently described (*i.e.,* not as part of a range) is 720 mg/day.
    - The specification discusses many dose ranges, including "100–1,000, 200–800, 240–720, and 480–720 mg/day."
    - The 480 mg/day dose is as "anchored" to the 720 mg/day dose as is 240 mg/day, which is both the lower end of a different range ("240–720") and a dose known to be ineffective.
    - Mylan's expert witness testified that the paragraph of the specification containing the "about 480 mg to about 720 mg per day" range fails to specifically link an effective dose of dimethyl fumarate to the treatment of multiple sclerosis.
    - The inventor on the priority application testified that his research could *not* be extrapolated to a clinical dose of dimethyl fumarate and that is it "was never the focus of [his] work to inform the clinical dosing of" dimethyl fumarate, suggesting that the research work that forms the basis for the specification would not be useful in identifying therapeutically effective doses.
- Biogen's expert lacked credibility because (i) he took the position in a related *inter partes* review that a skilled artisan would *not* have had a reasonable expectation that 480 mg/day would be therapeutically effective; and (ii) was evasive on this issue when testifying in this case.

The district court determined that "the Biogen expert's opinion that a skilled artisan would be drawn to a [480 mg/day] dose was neither credible nor persuasive," Biogen's attempt to rely on combining disparate disclosures

[1] The claims also allowed for the use of methyl fumarate and combination of methyl and dimethyl fumarate. The written description issue focused on the "arm" of the claim that covered use of dimethyl fumarate by itself.

[2] The pathway at issue relates to nuclear factor E2-related factor 2 (Nrf2), a transcription factor linked to induction of antioxidant and detoxification enzymes and protection of brain cells from damaging free radicals.

in the specification is an approach that "has been squarely rejected by the Federal Circuit," and Mylan had shown by clear and convincing evidence that the asserted claims were invalid for lack of written description.

Biogen appealed.

Background: Relevant Black Letter Law

1. Written Description - Basics
   a. Purpose:
      i. "The purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification."[3]
      ii. The written description requirement "serves a teaching function, as a 'quid pro quo' in which the public is given meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time."[4]
      iii. "Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention' – that is, conceive of and complete the final invention."[5]
   b. Analytic test:
      i. Primary formulation: Did the inventor have *possession* of the claimed invention as of the priority date?[6]
      ii. Alternative formulations (potentially useful for creative lawyering):
         1) A person of skill in the art reading the specification must be able to recognize that the inventor actually "invented" what is claimed.[7]
         2) A person of skill in the art reading the specification must be able to "visualize or recognize" the claimed invention.[8]
         3) Does the description identify the claimed invention in a definite way, such that a person of ordinary skill would understand that the inventor had "made" the invention at the time of filing?[9]
   c. Issue of fact for the jury (or judge in a bench trial – as occur in Hatch-Waxman cases).[10]
2. Written Description – "Possession" of the claimed invention
   a. "Possession" of the claimed invention is evaluated via an *objective* inquiry *based on the specification*.[11]
      i. Not sufficient to show lab notebooks, prototypes, etc. – the "hallmark" of written description is disclosure in the specification (*e.g.,* note the "quid-pro-quo" policy underlying the requirement).[12]
      ii. Possession of the claimed invention may be shown by "such descriptive means as words, structures, figures, diagrams, formulas, etc."[13]

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[3] *In re Katz Interactive Call Processing Patent Litig.,* 639 F.3d 1303, 1319 (Fed. Cir. 2011).

[4] *Univ. of Rochester v. G.D. Searle & Co., Inc.,* 358 F.3d 916, 922 (Fed. Cir. 2004) (quoting *Enzo Biochem, Inc. v. GenProbe Inc.,* 323 F.3d 956, 970 (Fed. Cir. 2002)).

[5] *Ariad Pharms., Inc. v. Eli Lilly & Co.,* 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

[6] *Ariad*, 598 F.3d at 1351 (The test is whether the disclosure "conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.").

[7] *QI Press Controls v. Lee,* 752 F.3d 1371, 1380 (Fed. Cir. 2014) (citing *Ariad*, 598 F.3d at 1351).

[8] *Allergan v. Sandoz,* 796 F.3d 1293, 1308 (Fed. Cir. 2015) (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 323 F.3d 956, 968 (Fed. Cir. 2002)).

[9] *Allergan,* 796 F.3d at 1308 (quoting *Ariad*, 598 F.3d at 1352).

[10] *E.g., Allergan,* 796 F.3d at 1308 (quoting *Alcon Research Ltd. v. Barr Labs., Inc.,* 745 F.3d 1180, 1190 (Fed. Cir. 2014)).

[11] *E.g., Ariad*, 598 F.3d at 1351 (written description analysis is an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art."). There are exceptions in which a patentee may rely on information that is "well-known in the art" to help demonstrate adequate written description. *E.g., Streck v. Research & Diagnostic,* 655 F.3d 1269, 1287 (Fed. Cir. 2012).

[12] *Ariad*, 598 F.3d at 1351-52 ("The term 'possession,' however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, 'possession as shown in the disclosure' is a more complete formulation" and "actual 'possession' or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession.").

[13] *Lockwood v. Am. Airlines, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997).

1) No need for *in haec verba* support in the specification – substance matters, not form.[14]

iii. "[A] description that merely renders the invention obvious does not satisfy the requirement."[15]

b. The analysis is dependent on the nature of the invention and the complexity of the relevant technology and is therefore highly fact-dependent.[16]

i. The fact-dependence of the analysis highlights the effect of the standard of review – *i.e.,* substantial evidence for jury determination, clear error for bench trials (as occur in Hatch-Waxman cases).

What *Biogen v. Mylan* Adds or Changes:

This case does not change the law of written description, but it emphasizes the weakness of developing post-hoc rationalizations about where and how the specification supports the claim language (as opposed to drafting the specification and claims with this issue in mind to begin with)[17] and the importance of standards of review. This case also nicely illustrates a classic tension between written description and obviousness.

Federal Circuit Found No "Clear Error" by the District Court

The Federal Circuit held that there was "no clear error in the district court's judgment that Mylan established its burden of showing, by clear and convincing evidence, that the asserted '514 Patent claims are invalid for lack of written description under 35 U.S.C. § 112." The key aspects of the court's reasoning were as follows:

- The court first assumed for sake of argument that a person of ordinary skill in the art would read the specification and conclude that the inventors had possession of the use of dimethyl fumarate for the treatment of multiple sclerosis. This is far from a foregone conclusion in light of the evidence, but it simplifies and focuses the analysis.
- The issue then became whether the claimed dosage was adequately described – *i.e.,* 480 mg/day as a therapeutically effective treatment for multiple sclerosis.
  - Looking at the specification from the perspective of a skilled artisan for guidance regarding a suitable therapeutic-dimethyl fumarate dosage, the written description presents problems:
    - The claimed 480 mg/day dose "is listed only once in the entire specification," as "the end of one range among a series of ranges" (*i.e.*, "of 100–1,000, 200–800, 240–720, and 480–720 mg/day").
    - That description of a 480 mg/day dosage is "in stark contrast to" the description of the 720 mg/day dose, which is referenced independently (*i.e.,* not as part of a range) and "was known to be effective as of the February 2007 priority date."[18]
    - Even if there were something in the specification pointing to 480 mg/day as effective, nothing in the specification links that sole reference to 480 mg/day to the treatment of multiple sclerosis.
  - The court credited the inventor's testimony that clinical dosing was not part of his research work and that the examples in the specification would not be helpful to identify a therapeutically effective dose, and also noted "the specification's focus on drug discovery and basic research."
  - The court deflected Biogen's assertions that the 480 mg/day dose was "anchored" to the known-to-be effective 720 mg/day dose by virtue of appearing in the same range by pointing out that the known-to-be *ineffective* 240 mg/day dose was "anchored" to the 720 mg/day dose in exactly the same way.
- In sum, the specification failed to provide sufficient data points to either (i) convince the district court that the inventor had possession of a therapeutically effective 480 mg/day dose for treatment of multiple sclerosis, or (ii) to

[14] *E.g., Purdue Pharma LP v. Faulding Inc.,* 230 F.3d 1320, 1323 (Fed. Cir. 2000).

[15] *Ariad*, 598 F.3d at 1352.

[16] *E.g., Synthes USA v. Spinal Kinetics*, 734 F.3d 1332, 1341 (Fed. Cir. 2013) (The "level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."). *See also Ariad,* 598 F.3d at 1351 ("Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.").

[17] For example, why did the specification not include narrower ranges and link the various dose ranges to effective treatment of multiple sclerosis? As another example, why did the claims not conform to the dose ranges explicitly disclosed? There might be good reasons that these ideas would not have been possible or advisable in this case, but these are among the obvious questions – and *prima facie* it seems that the specification and claims could have been better drafted.

[18] The effectiveness of 720 mg/day appears to have been brought into evidence by Biogen's expert witness and accepted as within the knowledge of a person of ordinary skill in the art.

provide the Federal Circuit a basis or finding clear error by the district court.[19] Another way of looking at the case is that there were insufficient "blaze marks" in the specification to point a person of skill to the 480 mg/day dose as therapeutically effective for treatment of multiple sclerosis.

Biogen Was Doomed, In Part, By Tension Between Obviousness and Written Description

The Federal Circuit also credited the district court's determination that Biogen's expert lacked credibility. In a related *inter partes* review in which obviousness of the claims was at issue, Biogen's expert contended that a person of skill in the art would not have reasonably expected a 480 mg/day dose to be therapeutically effective. That same expert contended at trial in the district court that a person of skill in the art would be drawn to the 480 mg/day dose, and when cross examined the expert became evasive.

Inconsistent statements on relevant, closely-related issues coupled with evasiveness calls the expert's credibility into question. Indeed, the district court expressly found the expert's testimony to be "neither credible nor persuasive" and the Federal Circuit could "discern no principled reason to disturb the district court's assessment as to the credibility of Biogen's expert testimony."

This situation illustrates a tension between obviousness and written description.[20] Here, how a person of ordinary skill would have viewed a 480 mg/day dose was a significant issue for both obviousness and written description. For obviousness purposes, Biogen wanted the 480 mg/day dose to appear (based on the prior art) to be remote, uninteresting, and unlikely to work to a person of skill – *i.e.,* not obvious. In contrast, for written description purposes Biogen wanted the 480 mg/day dose to be clearly visible (based on the specification) to a person of skill – *i.e.,* more than obvious. But the content of the prior art seems to have been roughly equivalent to the disclosure of the specification regarding the 480 mg/day dose. Hence the "trap" and the inconsistent statements in the two fora.

Finding a way to force this tension is a classic and often effective patent litigation strategy. What I do not understand is why Biogen did not use *separate experts* in the two fora. At very least the prior inconsistent statement credibility issue would not have arisen – and, if the expert witness was properly prepared to testify, the evasiveness problem could have been avoided.

[19] Once again, the standard of review created an uphill battle for the patentee (although it may not have been as decisive here as it has been in other cases).

[20] This kind of tension also exists, and is typically more pronounced (and more useful/dangerous), with respect to obviousness and enablement.